

Notice of Allowability

Application No.

10/685,266

Applicant(s)

TATSUMI ET AL.

Examiner

Dr. Kailash C. Srivastava

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 09/14/2006.
2. ☒ The allowed claim(s) is/are 19 and 20.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

Examiner's Amendment/Comment

1. Applicant's responsive amendment filed 14 September 2006 in response to Office action mailed 11 August 2006 is acknowledged and entered.
2. The Art Unit Location for your application under prosecution at the United States Patent and Trademark Office (i.e., USPTO) has been changed to Art Unit 1657. To aid in correlating any papers for this application (i.e., 10/685,266), all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1657.
3. In view of Applicant's amendments and response filed 14 September 2006, the following objections and rejections in Office Action mailed 11 August 2006 are hereby withdrawn:
 - Objection to Specification for not reciting the application Priority Data at Page1, Line 1 of the specification;
 - Objection to Title because the title of the invention as presented at that time did not conclusively summarize the elected and claimed invention;
 - Objection to Claim 18 as being improper;
 - Rejection to Claims 18-20 under Obvious Type Double Patenting in view of the teachings in Claims 9-12, U.S. Patent 5,620,994;
 - Anticipatory Rejections under 35 U.S.C§ 102 (b) to Claims 18-20 by U.S. Patent 5,820,994; and
 - Rejections under 35 U.S.C§§102 (f) and (g) to Claims 18-20 over U.S. Patent 5,820,994.

Claims Status

4. Claims 1-17 have been cancelled.
5. Claim 18 has been amended
6. Claims 18-20 are pending.

Examiner's Amendment

7. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR §1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

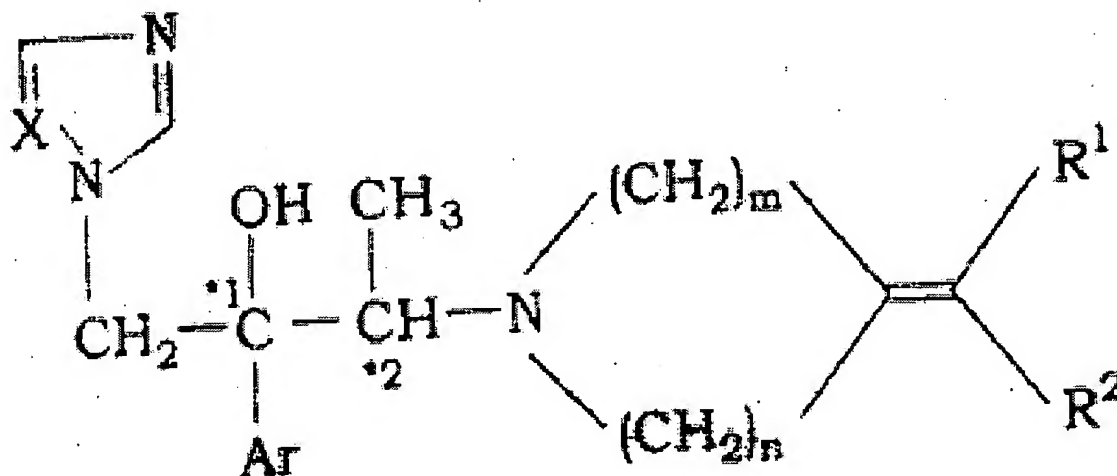
8. Authorization for this examiner's amendment was given in a telephone interview on 18 December 2006 with Mr. Ronald I. Eisenstein, Applicant's Representative.

In the Claims:

The following listings of the claims will replace all prior versions and listings of the claims in this application:

18. (Cancelled).

Claim 19 (CURRENTLY AMENDED): A method for treating a subject having onychomycosis wherein the method comprises topically administering to a nail of [a] said subject having onychomycosis [an] a therapeutically effective amount of an antifungal agent compound ~~having a group~~ represented by the following formula:



wherein, Ar is a non-substituted phenyl group or a phenyl group substituted with 1 to 3 substituents selected from a halogen atom and trifluoromethyl group,

R¹ and R² are the same or different and are hydrogen atom, C₁₋₆ alkyl group, a non-substituted aryl group, an aryl group substituted with 1 to 3 substituents selected from a halogen atom, trifluoromethyl group, nitro group and C₁₋₁₆ alkyl group, C₂₋₈ alkenyl group, C₂₋₆ alkynyl group, or C₇₋₁₂ aralkyl group,

m is 2 or 3,

n is 1 or 2,

X is nitrogen atom or CH, and

*1 and *2 mean an asymmetric carbon atom.

Claim 20 (PREVIOUSLY PRESENTED): The method of Claim 19, in which the compound represented by the formula (II) is (2R, 3R)-2-(2, 4-difluorophenyl)-3-(4-methylen piperidine-1-yl)-1-(1H-1, 2,4-triazole-1-yl) butane-2-ol.

Examiner's Reasons For Allowance

9. The following is an examiner's statement of reasons for allowance:

- o The closest art are:
 - U.S. Patent 5, 620, 994 issued 15 April 1997 to Naito et al., who teach a fungicidal composition comprising the same compounds, having the same structure as that claimed in the instant invention.

- US 20060003969 A1 Published 05 January 2006, Inventor: Manandhar, M.P. The invention is drawn to a method to treat pathogenic infections. The method does not teach topical administration of said composition wherein the composition penetrates the nail plate.
- US 20040197280 A1 Published 07 October 2004, Inventor: Repka, M.A. The invention is drawn to a method to deliver medicaments to nails to treat the infection. The method does not that the applied composition/medicament penetrates through he nail plate.

Thus, the cited prior or pertinent art teach treating a pathological infection, delivery of a medicament to nails, or treating the nail infection via topical and/ or systemic application of the medicament. In contrast the method claimed in instantly presented claims is a composition topically applied to the onychomycosis infection cite, wherein, unexpectedly and in contrast to previously evaluated compositions/methods, the instantly claimed method cures the onychomycosis because the medicament upon direct administration to the nail, penetrates through the nail plate and eradicates the infection at the site.


10. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

11. Claims 19-20 are allowed.

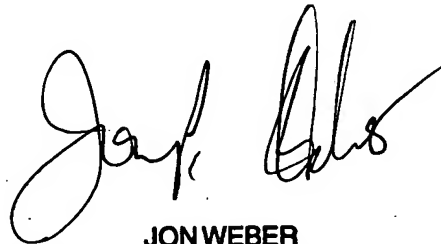
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

 Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1657
(571) 272-0923

December 26, 2006


JON WEBER
SUPERVISORY PATENT EXAMINER